



State of California—Health and Human Services Agency
Department of Health Services



RADIATION SAFETY ADVISORY 05-02

ARNOLD SCHWARZENEGGER
Governor

September 22, 2005

To: Fluoroscopic Radiation Machine Registrants

Subject: Mobile Fluoroscopic Equipment Exemption

This advisory addresses the ongoing concern of registrants and the Radiologic Health Branch (RHB) regarding the necessary use of mobile medical fluoroscopes intended for special surgical applications at source-skin distances of less than 30 centimeters. Such use allows medical staff to maintain patient safety, sterile fields, or achieve other unique surgical requirements. California Code of Regulations, title 17, Section 30307 (a)(8)(A) mandates the minimum source-skin distance requirement. The Department may grant exemptions from the requirements of California Radiation Control Regulations as it determines are authorized by law and will not result in any undue hazard to health, life, or property.

Physicians and fluoroscopy personnel are hereby granted an exemption to remove the spacer cones and operate at source-skin distances of not less than 20 centimeters for medical procedures in which the cone is contraindicated or compromises the procedure. This exemption is instituted so that California's regulations avoid conflict with the requirements of Title 21 Code of Federal Regulations, Part 1020.32. It also provides a means for the Registrant to maintain compliance with the regulations while providing safe care to their patients.

Compliance with the provisions listed below will be evaluated during inspections conducted by RHB personnel. This exemption remains in effect provided the following criteria are met:

1. The Registrant shall establish a policy and procedure that describes the use of the equipment under the conditions specified in this exemption. This shall include a list of procedures for which a physician deems spacer cone removal necessary.
2. The Registrant shall maintain the manufacturer's published precautions with respect to the spacer cone.

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3. All physicians and fluoroscopy personnel shall receive training regarding spacer cone use and restrictions. Documentation of training shall be maintained for inspection.
4. The spacer cone shall be reinstalled upon completion of the examination(s) for which removal is authorized.

Failure to maintain adequate safety measures may compromise patient safety. This exemption shall be revoked if the registrant does not adhere to the criteria set forth in this advisory. This advisory supercedes all previously issued exemptions to California Code of Regulations, title 17, Section 30307 (a)(8)(A) regarding medical fluoroscopes intended for special surgical applications and spacer cone use.

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